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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,277	02/13/2001	Dominique Therese Marie Frechon	P66034US0	5117

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EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	**PAPER NUMBER**
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/674,277	FRECHON ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-25 and 27-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-25 and 27-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

Applicants arguments filed 11-17-05 have been considered. In regard to the premature finality of the Office action mailed 6-21-05 the arguments are convincing. The finality of the Office action mailed 6-21-05 is withdrawn and the amendment to the specification and claims filed 11-17-05 have been entered into the record.

Claims 1-19, 26, and 31-60 have been cancelled. Claims 20-25 and 27-30 are pending.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

Claims 20, 21 and dependent claims 22-25 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

The objected to the specification under 35 U.S.C. 132(a) because it introduces new matter into the disclosure is withdrawn based on the new argument of record.

The rejection of claims 20-25 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment to the claims.

The rejection of claims 20-25 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of the amendment to the claims.

Rejections Maintained

Claims 20 and 21 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons made of record in the previous office actions and herein.

Applicants argue that compliance with the written description requirement does not require examples of such derived sequences be expressly be described in the specification. This is not persuasive, the courts have held that the specification must have a representative number of species to support a genus claim and that the written description of the specification must covey possession of the genus of derivatives. Applicants' have no written description for any of these other desirable compounds are not enabled for such and that applicants' are not entitled for dominance of further patentable inventions by claims that are insufficiently supported by the specification (*In re Fisher*, 166 USPQ 18, CCPA (1970)). The claims are drawn to a genus of nucleic acids wherein the genus is defined by hybridization conditions and therefore have an undefined structure in common. The scope of the claims encompass substantial variety of nucleic acids. The disclosure fails to provide sufficient description as to structural and functional features of the gnus, such as conserved regions that are critical to function and structure of the claimed genus. There is no description of the sites at which variability may be tolerated and there is no information with respect to structure and function of detection of enterohaemorrhagic *E. coli* microorganism, and 0157:H7 in particular as opposed to any other non-enterohaemorrhagic *E. coli* nucleic acid. It is noted that a significant portion of SEQ ID NO:1 and 2 are present in non-enterohaemorrhagic *E. coli* nucleic acid sequences and as such, hybridization conditions set forth in the claim does not define or particularly circumscribe those particular to enterohaemorrhagic *E. coli or any particular serotype* There is no known or disclosed correlation of SEQ ID NO:1 or 2 variants and function particular to detection of particular enterohaemorrhagic *E. coli.* Therefore, it cannot be said that the disclosed function of detection of enterohaemorrhagic *E. coli* is sufficiently correlated to a particular, known structure recited by hybridization conditions. With

respect to use of an assay (i.e. hybridization and detection) to support written description, the courts have held that disclosure of such screening assays having the desired activity, without disclosure of which polynucleotides have the desired characteristic, the claims failed to meet the written description requirement *University of Rochester v. G.D. Searle & Co.* 69 USPQ2D 1886 (CAFC 2004). Without any disclosure of what residues are required to function as claimed, the skilled artisan could not visualize or recognize the identity of the members of the genus that would be useful. The courts have held that when the specification discloses at most a specific DNA segment known to the inventor having a specific structure and biological characteristics, the disclosure is not commensurate in scope with the claims (*Ex parte Maizel*, 27 USPQ2d 1662).

The rejection is maintained for reasons made of record.

Claims 27-30 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reasons made of record in the rejection of record mailed 6-21-05.

Applicants response did not address the issues repeated herein with respect to the deposit and claims 27-30, Applicant's referral to the deposit of the clones pDF3 and pDF4 on page 5 of the specification is an insufficient assurance that all required deposits have been made and all the conditions of 37 CFR §1.801-1.809 have been met. If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made

under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. If the deposits *have not* been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR §1.801-1.809, assurances regarding availability and permanency of deposits are required. Applicant's attention is directed to In re Lundack, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR §1.801-1.809 for further information concerning deposit practice.

Claims 22-25 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention applicants is maintained for reasons made of record.

As to claims 22-25, the claims recite "the nucleic acid according to claim X" and it is not clear if the claims are intended to reference the "fragment" or "derived sequence". As such, it is not clear what alternative is specifically being limited in the dependent claims and therefore the dependent claims do not have proper antecedent basis or are properly dependent from independent claims 20 or 21.

As to claim 24, SEQ ID NOS:10 and 11, these sequences do not apparently have "at least a portion of IS91 and at least a portion of gene sequence katP, which appears to bridge residues 406-407 of SEQ ID NO:1 (see Figure 1). This issue is best resolved by Applicants pointing to the corresponding residues of each of these sequences that correspond to "the claimed "at least a portion of insertion sequence IS91" and "at least a portion of gene sequence katP".

Claim 20 stands rejected under 35 U.S.C. 102(b) as being clearly anticipated by Brunder et al (Microbiology, 146:3305-3315, 1996) for reasons made of record in the Office Action Mailed 12-13-03.

Applicants' arguments have been carefully considered but are still not persuasive. Applicants argue that claim 20 is clearly novel over Brunder et al as the subject matter allegedly found in the reference has been deleted from the claim. This is not persuasive, the sequence of Brunder has 2 substitutions and insertions 5' and 3' to SEQ ID NO:2. The term mutation includes one or more base insertions, the length of insertions is not defined in the specification and the sequence of Brunder et al would hybridize, absent convincing factual evidence to the contrary. The deletion of "mutation" from the claim would obviate the 102 issue with respect to Brunder et al.

Applicants' arguments with respect to claims 21, 22 and 24 are persuasive.

Claims 20 and 25 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Makino et al , (DNA Research, 5(1):1-9, Feb 28, 1998) ***in light of*** GenEMBL Accession Number AB011549 is maintained for reasons made of record.

Applicants' arguments are not persuasive. Applicants argue that the rejection can not be maintained because it relies upon more than one reference. Applicants are clearly erroneous and have misstated the rejection as in view of and not "in light of". The evidence provided by the in light of reference necessarily demonstrates that the prior art plasmid structure inherently meets the claim limitations.

Applicants' arguments have been carefully considered but are still not persuasive. Applicants argue that claim 20 is clearly novel over Makino et al as the sequence data was not reported in the reference, the accession number is not available as prior art as 102(b) and does not place the public in possession of the claimed invention. This is not persuasive, the plasmid of Makino has 2 substitutions and insertions 5' and 3' to SEQ ID NO:2. The term mutation includes one or more base insertions, the length of insertions is not defined in the specification and the sequence of Makino et al would hybridize, absent convincing factual evidence to the contrary. The deletion of "mutation" from the claim would obviate the 102 issue. The issue of when the actual sequence was available is simply not persuasive

of the issue as the intact plasmid was used against the claim and the specific sequence thereof is inherent to the plasmid. The GenEMBL accession number is merely provided to demonstrate *the property of inherency*. The sequence of the plasmid need not be actually described as by alphabet letters to be disclosed in the prior art. The sequence was in possession of the prior art as clearly shown by "A complete sequence" in the title of the reference and the reference is enabled for repeating the methodology and sequencing the complete plasmid. The reference inherently places the claimed invention in the public domain.

Applicants' arguments with respect to claims 21, 22 and 24 are persuasive.

Claims 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makino et al , (DNA Research, 5(1):1-9, Feb 28, 1998) in view of Schmidt et al, Microbiology 142(4):907-914, 1996 and Kennell et al 1971("Principles and properties of nucleic acid hybridization", Progr. Nucl. Acid Res. Mol. Biol. 11: 259-301) in light of GenEMBL Accession Number AB011549 .

Applicants argue that since Makino et al fails under 102, so does the rejection based thereon because the secondary references do not cure the deficiencies of Makino et al. This is not persuasive because obviation of a 102, does not obviate a 103 based on that rejection and there are no fatal deficiencies of Makino et al. The GenEMBL accession number was first available in the NCBI database July 23, 1998. It is maintained that the accession number is not required to derive fragments from the plasmid that hybridize to itself. Further, Makino et al is fully enabled for sequencing the complete plasmid to obtain the alphabet letter code designation of the native chemical sequence. There is nothing unobvious about using fragments of an existing plasmid to detect the plasmid *per se* or the organism from which it was derived. The fragments are obvious over the whole, absent unexpected results or a documented chemical difference between the claimed fragment and the plasmid of the prior art. In the instant case, it would have been

obvious make fragments derived from *E. coli* o157:H7 93-kb plasmid that have the expected property of hybridization to detect themselves. The art is enabled, there is nothing unexpected or unobvious in regard to the claimed fragments.

Status of Claims

All claims stand rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patricia A. Duffy
Primary Examiner
Art Unit 1645